

**REMARKS**

In the Office Action, the Examiner rejected claims 1-4, 6-16, and 18-22, and objected to claims 5 and 17. Applicant thanks the Examiner for the indication of allowable subject matter in claims 5 and 17. No claims are presently added or amended, and claims 23-27 were previously withdrawn. Reconsideration of the application in view of the remarks set forth below is respectfully requested.

**Rejections under 35 U.S.C. § 103**

The Examiner rejected claims 1-4, 6-16, and 18-22 under 35 U.S.C. § 103(a) as being obvious over Diab et al. (U.S. Publication No. 2003/0036689) in view of Swedlow et al. (U.S. Patent No. 5,662,106) and in further view of Chin et al. (U.S. Patent No. 6,018,673). Applicant respectfully traverses this rejection.

In the Office Action, the Examiner stated:

With respect to claims 1-4, 6-16, 18-22, the Diab et al. patent teaches a system for detecting the presence of mixed venous and arterial blood pulsation in tissue, (abstract, paragraph 0019), obtaining a measure of a phase different between said first and second electromagnetic radiation signals (paragraphs 0389-0391, fig. 25B, elements 694, 692, 690), comparing said measure with a threshold value to form a comparison (paragraph 0387, fig. 25B, elements 660, 662, 696); and detecting the presence or absence of venous pulsation using said comparison (paragraphs 0019, 0368). (NOTE: it is well known in the art that the primary cause of noise in transmissive pulse oximetry measurements is motion artifact caused by the movement of venous blood in the finger).

Diab et al. do not disclose indicating the presence of venous pulsation to a caregiver if venous pulsation is present. However, the Swedlow et al. patent teaches an indication of the presence of venous pulsation to a caregiver if venous pulsation is present (see abstract, fig. 1, element 30, and figure 4, col. 5, line 64 – col. 6, line 34).

Office Action, pages 2-3.

On a preliminary note, the Applicant stresses that while the Examiner indicated that the Chin reference was relied upon to reject claims 1-4, 6-16, and 18-22, the Office Action did not specifically identify passages in the Chin reference that could hypothetically correspond to any of the claimed subject matter. Accordingly, the Applicant respectfully reminds the Examiner that regulations state the following:

(2) In rejecting claims for want of novelty or for obviousness, the examiner must cite the best references at his or her command. When a reference is complex or shows or describes inventions other than that claimed by the applicant, the *particular part relied on must be designated as nearly as practicable*. The pertinence of each reference, if not apparent, must be clearly explained and each rejected claim specified.

37 C.F.R. § 1.104 (emphasis added).

Again, in the present Office Action, the Examiner failed to indicate what part of the Chin reference hypothetically corresponds to the claimed subject matter. Further, as noted in the prosecution history, the Chin reference merely illustrates Lissajous plots but does not disclose detecting the presence of venous pulsation using such plots. Accordingly, the Applicant believes that the Chin reference was mistakenly included in the Office Action as it was cited in previous Office Actions. That is, it appears that the Chin reference may have been accidentally cited as a result of the Examiner borrowing text from a previous Office Action. Regardless, in view of the Examiner's failure to directly assert the Chin reference, Applicant does not address this reference in the following remarks except to say that the Chin reference does not remedy the deficiencies of the other cited references. If the Examiner maintains this rejection and again cites the Chin reference, the Applicant respectfully requests that those elements from Chin which hypothetically correspond to the claimed subject matter be designated in a future non-final Office Action.

The burden of establishing a *prima facie* case of obviousness falls on the Examiner. *Ex parte Wolters and Kuypers*, 214 U.S.P.Q. 735 (B.P.A.I. 1979). To establish *prima facie* obviousness of a claimed invention, *all* the claim limitations must be taught or suggested by the prior art. *In re Royka*, 180 U.S.P.Q. 580 (C.C.P.A. 1974) (emphasis added).

In pulse oximetry, a phenomenon known as “venous pulsation” may interfere with the calculation of various physiological parameters, such as oxygen saturation or pulse rate. Application, paragraph 38. Venous pulsation is generally believed to be caused by venous blood backing up and pooling due to a lack of sufficient valves in the vascular anatomy. *Id.* Venous pulsation is more common in certain areas of the body where there are fewer valves, such as the head or forehead. *Id.* In addition, a patient’s medical condition may increase the likelihood that venous pulsation will occur. *Id.* Typically, caregivers are instructed to secure sensors to patients tightly enough to overcome any venous pulsation, but it is not easy to determine whether any particular sensor has been secured properly. Application, paragraph 39.

Accordingly, the present application is directed to detecting the presence of venous *pulsation* so that a caregiver may be notified and take measures to preclude the presence of further venous pulsations, e.g., by tightening the sensor on the patient. As such, independent claim 1 recites, *inter alia*, “detecting the presence or absence of venous pulsation ... and indicating the presence of venous pulsation to a caregiver if a venous pulsation is present.” Independent claim 13 recites, *inter alia*, “means for detecting the presence or absence of venous pulsation ... and means for indicating the presence of venous pulsation to a caregiver when venous pulsation is present.”

In contrast, the Diab reference discloses a system where the venous *saturation* is quantified. Specifically, the Diab reference calculates an arterial saturation and a venous saturation. *See* Diab, paragraph 395. To measure the venous saturation, the Diab reference uses arterial saturation values, and the venous saturation measurement appears to derive from arterial saturation measurements. *See id.* The Diab reference explains:

In order to obtain the venous saturation, the minimum arterial saturation value, of points that exhibit non-zero value, is selected rather than the maximum arterial saturation value. The saturation can be provided to the display 336.

Diab, paragraph 395. Applicant finds no discussion in the Diab reference regarding specifically detecting the presence or absence of a venous *pulsation*. Furthermore, the Diab reference clearly does not disclose that an indication of venous pulsation is provided to a caregiver for any reason.

Indeed, the Examiner stated, “Diab et al. do not disclose indicating the presence of venous pulsation to a caregiver if venous pulsation is present.” Office Action, page 3.

The Swedlow reference does not cure the deficiencies of the Diab reference. In the Office Action, the Examiner stated that “the Swedlow et al. patent teaches an indication of the presence of *venous pulsation* to a caregiver if *venous pulsation* is present (see abstract, fig. 1, element 30, and figure 4, col. 5, line 64 – col. 6, line 34).” Office Action, page 3 (emphasis added). However, the cited passages do not mention venous pulsation. In fact, Applicant stresses that nothing in the Swedlow reference discloses detection of *venous pulsation*, much less an indication of its presence. Rather, the Swedlow reference merely discloses a pulse oximeter that detects *motion*. See Abstract; col. 1, lines 10-13; col. 2, lines 52-53. That is, the Swedlow reference relates to detection of a motion artifact, “such as by the detector moving away from the skin temporarily.” Col. 2, lines 14-15. Motion artifacts are not venous pulsations.

In the Office Action, the Examiner attempted to equate venous pulsation to motion artifact, stating that “it is well known in the art that the primary cause of noise in transmissive pulse oximetry measurements is motion artifact caused by the movement of venous blood in the finger.” Office Action, page 3. In view of this assertion by the Examiner, Applicant believes the Examiner is confused about the phenomena of venous pulsation and motion artifact. The Applicant asserts that this conclusory statement by the Examiner is not only unsupported by any evidence, but it is also clearly erroneous.

Venous pulsations and motion artifacts are clearly *not the same*. Interference with pulse oximetry readings may be caused by a wide variety of sources, such as, but not limited to, venous pulsation, physical movement of the patient, dysfunctional hemoglobin, low perfusion, intermittent pulsatility or arrhythmia, electromagnetic interference, ventilator-induced pressure changes, or ambient light. Each of these sources of interference is caused by different phenomena and may be handled differently. For example, as discussed above, and as addressed in the present application, *venous pulsation* is a phenomenon caused by a patient’s vascular anatomy and aggravated by some medical conditions or procedures. See Application, page 9,

paragraph 38. A *motion artifact*, on the other hand, is due to movement of the sensor with respect to the patient. *See, e.g.*, Swedlow, col. 2, lines 11-15.

Essentially, the Examiner has apparently taken Official Notice of supposed facts outside of the record that the Examiner apparently believes are capable of demonstration as being “well-known” in the art. Therefore, in accordance with M.P.E.P. § 2144.03, the Applicant hereby seasonably traverses and challenges the Examiner’s use of Official Notice. Furthermore, Applicant emphasizes that the Examiner’s assertions are plainly incorrect.

If the Examiner maintains a similar rejection in any future Office Action, the Applicant respectfully requests that the Examiner produce evidence in support of the Examiner’s position as soon as practicable during prosecution and that the Examiner add a reference to the rejection in the next Office Action. If the Examiner finds such a reference and applies it in combination with the presently cited references, the Applicant further requests that the Examiner specifically identify the portion of the newly cited reference that discloses the allegedly “well known” elements of the instant claim, as discussed above, or withdraw the rejection. If the Examiner relies only on personal knowledge, then the Applicant respectfully stresses that the Examiner must provide an affidavit or declaration in support of such personal knowledge. *See id.*

In addition, the Applicant submits that the Examiner’s use of Official Notice is improper on a legal basis, because the Official Notice is a broad sweeping statement. Section 2144.03 of the Manual of Patent Examining Procedure specifically states:

In *limited circumstances*, it is appropriate for an examiner to take official notice of facts not in the record or to rely on “common knowledge” in making a rejection, however such rejections should be *judiciously applied*.

...

As noted by the court in *In re Ahlert*, 424 F.2d 1088, 1091, 165 USPQ 418, 420 (CCPA 1970), the notice of facts beyond the record which may be taken by the examiner must be “*capable of such instant and unquestionable demonstration as to defy dispute*” (citing *In re Knapp Monarch Co.*, 296 F.2d 230, 132 USPQ 6 (CCPA 1961)).

...

For example, assertions of technical facts in the areas of esoteric technology or specific knowledge of the prior art *must always be supported by citation to some reference work* recognized as standard in the pertinent art. *In re Ahlert*, 424 F.2d at 1091, 165 USPQ at 420-21.

...

Furthermore, as noted by the court in *Ahlert*, any facts so noticed should be of notorious character and serve only to “fill in the gaps” in an *insubstantial manner* which might exist in the evidentiary showing made by the examiner to support a particular ground for rejection.

M.P.E.P. (Rev. 5, August 2006) § 2144.03, Pages 2100-133-136 (emphasis added). In view of these passages, the Applicant reiterates that the Examiner’s use of Official Notice is improper and cannot stand. Accordingly, despite the Examiner’s apparent attempt to equate venous pulsation with motion artifact, the cited references are deficient with respect to detecting and indicating the presence of venous pulsations.

In view of the remarks set forth above, Applicant asserts that the Diab reference, the Swedlow reference, and the Chin reference, whether taken alone or in hypothetical combination, do not render obvious the present claims. Accordingly, the Applicant respectfully requests withdrawal of the rejection under 35 U.S.C. § 103. Further, the Applicant requests that the Examiner provide an indication of allowance for all of the pending claims.

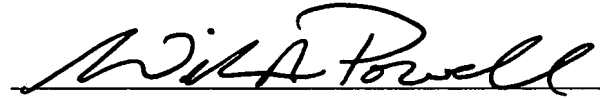
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**Conclusion**

In view of the remarks set forth above, the Applicant respectfully requests reconsideration of the Examiner's rejections and allowance of all pending claims. If the Examiner believes that a telephonic interview will help speed this application toward issuance, the Examiner is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,

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